**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**TAMPA DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v. CASE NO: 8:03-cv-1663-T-26MSS

PHARMAKON LABORATORY, INC.,
ABELARDO L. ACEBO, and
EDWARD R. JACKSON,

Defendants.
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**O R D E R**

On August 6, 2003, the United States initiated this action for preliminary and permanent injunctive relief against Defendants pursuant to 21 U.S.C. §332(a) of the Federal Food, Drug, and Cosmetic Act (the Act).[1] The United States' core concern was to enjoin Defendants from manufacturing and distributing adulterated drugs because the methods and facilities utilized in the manufacturing and distribution process of those drugs failed to conform to current good manufacturing practices (CGMP's).

On October 1 and October 2, 2003, the Court conducted a hearing on the United States' motion for preliminary injunction, following which the Court entered an order granting the

[1] See docket 1.

motion in part and denying the motion in part.[2] The Court's order allowed Defendants to continue drug manufacturing operations while being monitored by officials of the Food and Drug Administration (FDA) and a court-approved auditor.

On September 14, 2004, the United States sought leave of Court to amend its complaint to include allegations based on facts uncovered during the discovery process that Defendants were introducing into interstate commerce new drugs that were not approved by the FDA and which were not properly labeled pursuant to the Act.[3] The Court granted the motion on October 22, 2004.[4]

On June 7, 2005, following the conclusion of a six-day bench trial, the Court announced on the record pursuant to Rule 52(a), Federal Rules of Civil Procedure, oral findings of fact and conclusions of law in which it determined that judgment should be entered for the United States. The Court, however, reserved jurisdiction to enter a permanent injunction and directed the parties to furnish proposed injunctive orders and responses to the proposed orders.[5]

The Court has now had an opportunity to review the parties' proposed injunctive orders and their responses to those orders and to reflect again on the evidence, testimony, and arguments presented during the course of the bench trial. After doing so, the Court concludes that the United States' proposed injunction should be entered but with modifications with respect

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[2] See docket 29.

[3] See docket 64.

[4] See docket 76.

[5] See docket 153.

to the assessment of attorneys' fees, costs, and expenses incurred by the United States in implementing the injunction[6] and the procedure to be followed in reviewing any decision of the FDA.[7]

Although the Court is cognizant of Defendants' contention that to enter this order will effectively usher in the demise of Defendant Pharmakon Laboratory resulting in the loss of employment for a significant number of its employees, the Court simply cannot ignore the facts that clearly demonstrate Defendants' continued and substantial violations of the CGMP's even after this Court afforded it every opportunity to come into compliance with those regulations. Nor can the Court ignore the unrefuted evidence that Defendants, while these proceedings were ongoing, took it upon themselves to commence the manufacturing and distribution of certain unapproved and mislabeled drugs.

Finally, the Court would be derelict in its duty if it ignored the persuasive authority of United States v. Sage Pharmaceuticals, Inc., 210 F. 3d 475 (11th Cir. 2000), the facts of which mirror the facts in this case. As in Sage, the plain language of the Act mandates that Defendants not sell new drugs without FDA approval. Id. at 480. As in Sage, Defendants have failed to demonstrate any legitimate justification for avoiding the clear mandate of the Act. Id.

Although, as noted, the effects of the permanent injunction proposed by the United States may engender harsh consequences for Defendants, the refusal to enter such an injunction, which correctly places the onus on Defendants to comply with the Act and is consistent with

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[6] Compare paragraphs 9, 11, and 19 of the proposed injunction with paragraph 21 of the Court's injunction.

[7] Compare paragraph 20 of the proposed injunction with paragraph 19 of the Court's injunction.

injunctions entered by other United States District Courts,[8] may also have harsh consequences for members of the drug-consuming public. Under the facts presented, the Court is simply unwilling as a court of equity to place the health, safety, and welfare of the general public at risk in order to accommodate the economic well-being of Defendants who have been afforded every opportunity to come into compliance with the Act but who for some reason have failed to do so. Accordingly, the Court will enter by separate order the permanent injunction proposed by the United States as modified.

**DONE AND ORDERED** at Tampa, Florida, on July 25, 2005.

s/
**RICHARD A. LAZZARA**
**UNITED STATES DISTRICT JUDGE**

**COPIES FURNISHED TO**:
Counsel of Record

[8] See, e.g., United States v. Syntax Innovations, Inc., 149 F. Supp. 2d 880, 884 (E.D. Mo. 2001) (and cases cited).